## 510(k) SUMMARY

MAY 3 1 2013

### Submitter Information


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| Submitter's Name: | OrthoHelix Surgical Designs, Inc. |
| Address: | 1065 Medina Rd, Suite 500<br>Medina, Ohio 44256 |
| Telephone Number: | 330-869-9562 |
| Fax Number: | 330-247-1598 |
| Prepared By: | Brian Hockett, Liz Altenau |
| Contact Person: | Derek Lewis |
| Date Prepared: | 2/24/2013 |


### Device Information

| | |
|---|---|
| Trade Name: | MaxTorque™ Screw System |
| Common Name: | Fixation Screws |
| Classification Name: | Screw, Fixation, Bone<br>Washer, Bolt Nut |
| Device Classification: | Smooth or threaded metallic bone fixation fastener<br>Class II per 21 CFR 888.3040<br>Panel: Orthopedic, Product Code: HWC<br><br>Single/Multiple component metallic bone fixation appliances and accessories<br>Class II per 21 CFR 888.3030<br>Panel: Orthopedic, Product Code: HTN |
| Material Composition: | Titanium Alloy |
| Device Description: | The submission is a modification to the MaxTorque™ Screw System to add additional screw styles and lengths. No modifications were made to the existing implants. The MaxTorque™ Screw System consists of screws of various diameters, lengths and thread configurations. The system also includes correspondingly sized washers, the use of which is optional. |
| Intended Use: | The MaxTorque™ Screw System is intended to stabilize and aid in the repair of fractures, fusions, and osteotomies for small bones and bone fragments. |
| Substantial Equivalence: | The new MaxTorque™ Screws are substantially equivalent to the existing OrthoHelix MaxTorque™ Screw System (K082574 & K060428), the Asnis III Cannulated Screw System (K000080), the Asnis III Micro Cannulated Screw System (K071092), the Smith and Nephew Cannulated Screws and Washers System (K111994) and the Synthes Headless Compression Screw System (K080943). The submission is a modification to the MaxTorque™ Screw System to add additional screw styles and lengths. Calculations and finite element analysis comparing the strength of the subject and predicate devices were performed and the results support substantial equivalence. Due to similarities in indications, design, and materials, no other testing was required. No new issues of safety and effectiveness have been raised. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

May 31, 2013

OrthoHelix Surgical Designs, Incorporated
% Mr. Brian Hockett
1065 Medina Road, Suite 500
Medina, Ohio 44256

Re: K131324
Trade/Device Name: MaxTorque™ Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: May 21, 2013
Received: May 22, 2013

Dear Mr. Hockett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin D Keith

Mark Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K131324

Device Name: MaxTorque™ Screw System

Indications for Use:
The MaxTorque™ Screw System is indicated for use in long and small bone fracture, fusion, and osteotomy fixation, which includes but is not limited to the following:

- Fractures of the tarsal and metatarsals
- Fractures of the olecranon, distal humerus
- Fractures of the radius and ulna
- Patellar fractures
- Distal tibia and pilon fractures
- Fractures of the fibula, medial malleolus, os calcis
- Tarso-metatarsal and metatarsal-phalangeal Arthrodesis
- Metatarsal and Phalangeal osteotomies
- Osteochondritis dissecans
- Ligament fixation
- Other small fragment, cancellous bone fractures and osteotomies

Prescription Use ___X___ AND/OR Over-The-Counter-Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices